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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,417	06/14/2000	Raymond Andersen	108281-00001	8238

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/593,417

Applicant(s)

ANDERSEN ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☒ Claim(s) 8 and 10-13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 13
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Pursuant to the directives of paper No. 19 (filed 7/16/03), claims 1-4 and 9 have been amended, and claim 13 added. Claims 1-4, 8-13 are now pending.

Claims 2-4 remain withdrawn from consideration as being drawn to non-elected subject matter. The response filed 7/16/03 questions the examiner's assertion that claims 2-4 constituted non-elected subject matter. It is argued that claims 2-4 must be subgeneric to claim 1 since they are recited to be dependent thereon. However, claims 2-4 are not subgeneric to claim 1. Claim 1 requires that when  $R_{71}$  is hydrogen,  $R_{70}$  cannot be hydrogen. By contrast, each of claims 2-4 recite that  $R_{70}$  and  $R_{71}$  "**independently** represent a hydrogen atom or...". Claim 1 does not permit  $R_{70}$  and  $R_{71}$  to "independently" represent a hydrogen atom, but instead states that the option for  $R_{70}$  to represent hydrogen is **dependent** on what  $R_{71}$  represents. Accordingly, claims 2-4 encompass peptides that contain tryptophan (as opposed to, e.g., *beta*-methyltryptophan or *beta*, *beta*-dimethyltryptophan). Accordingly, claims 2-4 constitute non-elected subject matter.

Claims 1 and 8-13 are examined in this Office action.

Applicants' arguments filed 7/16/03 have been considered and found persuasive. The rejection of claim 9 under 35 U.S.C. §112, first paragraph, is withdrawn. The rejection of claim 1 as anticipated by Crews (*J. Org. Chem.* **59**, 2932, 1994) is withdrawn. Claims 8 and 10-13 are objected to because of their dependence on rejected claims.

※

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

※

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Huang (*J Am Chem Soc* 114, 9390, 1992)

Huang discloses (page 9400 col 1) the following peptide ("MeTrp" is *beta*-methyltryptophan):

Phe-Pro-Phe-MeTrp-Lys(Fmoc)-Thr

The claim is anticipated when the substituent variables correspond as follows:

R<sub>1</sub> = hydrogen  
R<sub>2</sub> = hydrogen  
R<sub>3</sub> = butyl substituted with fluorenylmethoxycarbonylamino  
R<sub>6</sub> = substituted acyl (i.e., the tripeptide Phe-Pro-Phe)  
R<sub>7</sub> = hydrogen  
R<sub>70</sub> = methyl  
R<sub>71</sub> = hydrogen

R<sub>72</sub> = hydrogen  
R<sub>73</sub> = hydrogen  
R<sub>75</sub> = substituted alkyl  
n = zero

Further explanation is provided with respect to variable R<sub>75</sub>. The disclosed peptide is encompassed when R<sub>75</sub> is substituted alkyl, more specifically a methyl group that is substituted first with oxo, then with the amino acid threonine. The prior art peptide is also encompassed when R<sub>75</sub> is -CH<sub>2</sub>-COX in which the "-CH<sub>2</sub>-" group is "substituted" with the side chain of threonine.

Thus, the claim is anticipated.

\*

Claims 1 and 9 are rejected under 35 U.S.C. §102(e) as being anticipated by Morriello (USP 5,721,250).

Morriello discloses the structure of a compound at col 19, lines 31-44. (Pharmaceutical compositions are disclosed, e.g., at col 160, line 23). The claim is anticipated when the substituent variables correspond as follows:

R<sub>1</sub> = hydrogen  
R<sub>2</sub> = hydrogen  
R<sub>3</sub> = substituted ethyl  
R<sub>6</sub> = substituted acyl (i.e., *alpha, alpha*-dimethylglycine);  
R<sub>7</sub> = hydrogen  
R<sub>70</sub> = methyl  
R<sub>71</sub> = hydrogen  
R<sub>72</sub> = hydrogen  
R<sub>73</sub> = hydrogen

$R_{74}$  = substituted ethyl  
 $R_{75}$  =  $-Q'-COX$   
 $Q'$  = substituted  $-CH_2-CH_2-$   
 $X$  =  $NH-C_2H_5$   
 $n$  = zero

Further explanation is provided with respect to variable  $Q'$ . As indicated, the prior art compound is encompassed when  $Q'$  is a group  $-CH_2-CH_2-$  that is "substituted". By "substituted" is meant that the methylene group which is bonded to  $-COX$  is substituted first with benzyl, and then with variable  $R_{74}$ . Variable  $R_{74}$ , in turn, is an ethyl group (which is bonded to a nitrogen atom). When the methylene group which is bonded to  $-COX$  is substituted with variable  $R_{74}$ , the result is a piperidine ring.

Thus, the claim is anticipated.

[It is noted that the application claims priority to GB 9508195.6, filed 4/20/95. However, the subgenus to which this rejection is directed was not described in that document. Thus, priority for this aspect of the claimed invention extends back only to 4/22/96].



References "AI" and "AJ" of the IDS (filed 10/30/02) were not considered. The documents should be uniquely identified, and the year of publication should be included in the citation.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*D. Lukton* 6/27/03

*Christopher S. Low*

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